

## REMARKS

Entry of the foregoing amendments, reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested. By the present amendment, the specification is amended at page 1, line 1 to update the patented status of the parent application.

Turning now to the Office Action, the objection to the specification at page 1 is noted. The objection is moot in view of the present amendment.

Claims 21-32 are rejected under 35 USC § 112 first paragraph as lacking support from the disclosure. This rejection is respectfully traversed as it is not well taken.

It is difficult to understand why this rejection was made when the disclosure at page 13, line 20 (considered by the Examiner) expressly indicates that PGCs were cultured "in the absence of feeder cells". Whether the use of feeder cells is optional is irrelevant to the § 112 rejection.

Quite clearly, the inventors contemplated culture in the absence of feeder cells and indeed reduced this embodiment to practice (note past-tense description "applicants cultured PGCs in the absence of feeder cells"). What the specification suggests is that while suspension culture in the presence of the recited constituents provides for PGC maintenance, that the use of feeder cells may also be useful. Indeed, the Examiner would have been on stronger ground had he suggested that the use of feeder cells lacked support from the disclosure (however, quite clearly this

embodiment also finds written description support at page 13, line 23 to page 14, line 11).

Moreover, the fact that the specification expressly indicates that feeder cells did not improve the long term culture of PGCs (page 27, line 14) further indicates that the rejection is quite simply misplaced. Again, this disclosure indicates that the inventors envisioned culture of PGCs in the absence of feeder cells, reduced it to practice, and established that it achieved similar results as culture in the presence of feeder cells.

Likewise maintaining the cells for 28 days or 4 months finds explicit support in the disclosure. Note particularly original claims 7 and 8 which part of the as-filed disclosure.

Further the functional linkage of a DNA encoding a polypeptide “to expression regulatory sequences that are operable in an avian cell” finds explicit support at page 17, lines 5-7 and 17-20. Applicants further specifically submit that the disclosure makes expressly clear that the regulatory sequences can be of generic eukaryotic origin, preferably avian, *e.g.*, “promoter operable in avian cells”. (See page 17, lines 22-24)

Withdrawal of the § 112 first paragraph rejection of claims 21-32 is respectfully requested.

Claims 31-32 stand rejected as not enabling culture conditions “to maintain cells for 14 days, 28 days, or 4 months”.

For the reasons et forth above, the specification does make clear that PGCs were cultured in the absence of feeder cells.

Moreover, the specification teaches at length culture conditions which provide for prolonged maintenance of PGCs in the absence of feeder cells, namely by the use of a culture medium that contains the four recited growth factor substituents, i.e., LIF, bFGF, SCF, and IGF. That this is sufficient to result in prolonged maintenance of PGCs is clear from the examples in the specification. Note especially, the disclosure at page 29, lines 20-24, which indicates that these growth factors maintained “PGC cells in culture for up to four months.”

Also, as noted above, the specification teaches explicitly at page 27, line 14, that feeder cells did not improve the long culture of PGCs. Based on this disclosure, withdrawal of the rejection is respectfully solicited unless the Examiner has any evidence to dispute the express teachings of the specification.

Claims 21-32 stand rejected under 35 USC § 112 second paragraph. This rejection is respectfully traversed.

The recitation in claim 21, “at least the following growth factor... feeder cells” is not superfluous. It is recited to make explicitly clear that the four factors are

necessarily present but that other constituents may also be present in the culture media.

The other objections to the phrasing of claim 21 are also traversed. The preamble of claim 21 is not inconsistent with step (ii) of the claim. Indeed step (ii) recites culturing.

Also, the phrasing of claims 22, 23 and 29 are not grammatically incorrect and would be clearly understood by a skilled artisan.

Claim 26 has been cancelled to cure this objection.

Finally, claim 32 is also not grammatically incorrect in its phraseology and would be clearly understood by a skilled artisan.

Claims 21-28, 30 and 31 stand rejected under 35 USC § 102(b) as being anticipated by Pain alone or in view of Simkiss. This rejection is traversed.

As previously argued during prosecution of the parent application, Pain et al., describes culture of putative ES cells derived from blastodermal cells. The reference does not teach a method for maintaining PGCs in culture for at least 14 days in the absence of feeder cells.

Moreover, contrary to the rejection, Pain et al. makes quite clear at page 2375 right column that their long-term culture conditions “included the use of mouse embryonic feeder cells.” This is explicitly taught in the reference.

Likewise, Simkiss does not cure the deficiencies of the § 102 rejection. Whether avian blastodermal cells from stage X embryos may contain PGCs does not suggest that Pain et al. teaches maintaining PGCs for at least 14 days in the absence of feeder cells.

Claims 21-32 stand rejected under 35 USC § 103 as being obvious under Pain et al. (online cite) unlike or Pain et al (Aug. 1996) as supported by Simkiss and Han et al. This rejection should be withdrawn.

First, the rejection is incorrect in the assertion that Pain et al. culture PGCs in the absence of feeder cells for 160 days. Again, the Examiner is requested to consider the contrary teaching at page 2345 right hand column. It is explicit that their long-term culture methods included feeder cells.

The secondary references do not cure the rejection. It is acknowledged that Han et al. teaches transfection of PGCs, but Han like Pain does not teach the claimed culture method for maintaining PGCs for at least 14 days.

Nor does Simkiss, which is only cited to teach that avian blastodermal cultures may contain PGCs.

Based on the foregoing, withdrawal of the § 103(a) rejection of claims 21-32 is respectfully requested.

Claims 21-32 also stand rejected on double patenting grounds based on the claims of US Patent 6,156,569 alone or in view of Pain. (Paragraph numbers 7, 8, 9 in Office Action).

These rejections are traversed on the basis that the allegedly conflicting claims do not recite the absence of feeder cells. As noted, supra, the Examiner has concluded that this embodiment is not contemplated by the prior claims, otherwise why would the subject claims be rejected as allegedly lacking written description support from the as filed claims, now patented in the earlier '569 patent?

The addition of Pain does not cure the rejection. For the reasons of record, Pain et al. does not teach prolonged culture and maintenance of PGCs as claimed. Withdrawal of the double patenting rejections based on Patent No. 6,156,569 above or in view of Pain are respectfully requested.

Finally claims 21-32 stand provisionally rejected based on claims of US Serial No. 09/127,624.

This rejection is respectfully traversed on the basis that the alleged conflicting claims do not anticipate or render obvious the claimed prolonged PGC culture conditions effected in the absence of feeder cells.

Withdrawal of the provisional double patenting rejection is respectfully traversed.

Based on the foregoing, this application is believed to be in condition for allowance. A Notice to that effect is respectfully solicited.

If there are any questions regarding this reply or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #100375/54723US).

Respectfully submitted,

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